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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,456	02/19/2004	Denisa D. Wagner	CFBF-P02-015	5162

7590 09/21/2006

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,456	WAGNER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 50-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22, 50-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 2/19/04, has been entered.
Claims 23-49 have been canceled.
Claims 50-56 have been added.

Claims 1-22 and 50-56 are pending.

2. The following is noted: The instant claims encompass methods of inducing hemostasis and/or of treating disorders associated with hypocoagulation or vasculature-associated diseases by administering "an inducer or P-selectin activity". The instant claims as well as the instant specification encompass various distinct molecules such as P-selectin polypeptides, nucleic acids encoding P-selectin polypeptides, anti-PSGL-1 antibodies and small molecules, for example. The examiner notes that these molecules do not share a substantial structural feature essential to a common utility.

Applicant is invited to clarify the intent and scope of "the inducer of P-selectin activity is an antibody to a P-selectin receptor or ligand" recited in instant claim 6.

For example, this "recitation" is ambiguous as to whether the terms "receptor" and "ligand" are intended to encompass different specificities or to provide alternatives in describing "P-selectin itself" (or "P-selectin polypeptide" itself).

From a brief review of the instant specification, the Restriction set forth this claim "recitation" as it reads on "anti-PSGL-1 antibodies" only.

If claims to structurally distinct molecules are intended or presented during the course of prosecution, they will be subject to a restriction requirement.

Further, it is noted that claim 50 recites "small molecules", peptides, peptidomimetics and antibodies.

For Restriction purposes, the antibody in claim 50 reads on anti-PSGL-1 antibodies.

"Peptides" and "peptidomimetics" are set forth in separate Groups.

If claims to structurally distinct molecules are intended or presented during the course of prosecution, they will be subject to a restriction requirement.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 9, 16, 50, 52, 53; drawn to methods of treating hemostasis and disorders with P-selectin, classified in Class 514, subclass 8.

II. Claims 6, 8, 50; drawn to methods of treating hemostasis and disorders with PSGL-1- specific antibodies, classified in Class 424, subclass 130.1.

III. Claims 10; drawn to methods of treating hemostasis and disorders with nucleic acid molecule encoding P-selectin, classified in Class 514, subclass 44.

IV. Claims 11; drawn to methods of treating hemostasis and disorders with a recombinant cell expressing soluble P-selectin, classified in Class 424, subclass 93.7.

V. Claims 50; drawn to methods of treating hemostasis and disorders with a small molecule(s), classified in Class 514, subclass 885.

VI. Claims 50; drawn to methods of treating hemostasis and disorders with peptide(s), classified in Class 514, subclass 2.

VII. Claims 50; drawn to methods of treating hemostasis and disorders with "peptiodmimetics", classified in Class 514, subclass 8.

VIII. Claims 20-21; drawn to methods of treating a disorder with a molecule comprising a first and second binding region, operatively linked to a coagulant; classified in Class 424, subclass 136.1.

IX. Claims 53-55, drawn to compositions comprising P-selectin, classified in Class 514, subclass 8.

X. Claims 56, drawn to compositions comprising inducing small molecule, classified in Class 514, subclass 885.

4. Inventions IX-X and I and V are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, there are a variety of products and compositions which are useful for inducing hemostasis and treating disorders associated with hypocoagulation and vasculature-associated diseases, which do not rely upon P-selectin and small molecules, for example. Further, such inducing agents can be employed in various biological assays and as detection or affinity agents.

5. Inventions I-VIII are directed to related methods of inducing hemostasis and treating disorders associated with hypocoagulation and vasculature-associated diseases.

Inventions IX-X are directed to related inducers of P-selectin activity.

The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed s. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I-VIII are different methods, which require patentably distinct ingredients, method steps and endpoints. These methods rely upon inducing agents that differ in structure, functional properties and modes of action. Also, it is noted that these molecules do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

Inventions IX-X are different products which are distinct because their structures and modes of action are different, which require non-coextensive searches. it is noted that these agents do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

6. Claims 1-5, 7, 12-15, 17-18 and 22 link inventions I-VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), 1-5, 7, 12-15, 17-18 and 22. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Because these inventions are distinct for the reasons given above and the search required for any Group from Groups I-X is not required for any other group from Groups I-X and Groups I-X have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

8. If applicant elects a Group from Groups I-VIII,
this application contains claims directed to the following patentably distinct species of the claimed Invention: wherein the P-selectin activity that is induced is:
A) increases the level of P-selectin in the plasma,
B) increases the proteolytic cleavage of P-selectin from a cell surface,
C) increases P-selectin gene expression, or
D) binds to P-selectin receptor or ligand and mimics the activity of P-selectin.

These species are distinct because the characteristics of the P-selectin activity differ and reflect distinct pathways and molecules. Therefore, they are separate and patentably distinct species issues in determining patentability.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Alternatively, applicant is invited to indicate or admit that these species are obvious variants on the record.

9. If applicant elects a Group from Groups I-VIII,
then applicant is required to elect a targeted disease or disorder targeted by the instant methods.

This application contains claims directed to the following patentably distinct species of the claimed Invention: wherein the disease or disorder is selected from those claimed or disclosed on pages 9-12 of the instant specification (e.g. hemophilia A, malignant tumors, psoriasis, rheumatoid arthritis, etc.).

These species are distinct because their etiologies and therapeutic endpoints are differ. Therefore, they are separate and patentably distinct species issues in determining patentability.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C.

101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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